Remarks

The claims stand rejected under 112 (second paragraph) for reasons stated on page 2 of the Office Action. Claim 7 has been amended to delete the phrase "and optionally also" overcoming the 112 rejection. Claim 12 stands rejected under 112 (second paragraph) for failure to set forth any steps involved in a method/process. Claim 12 has been cancelled in lieu of new Claim 27 which sets forth a method.

The cancellation of Claim 12 obviates the 35 USC 101 rejection.

Claims 1-12 and 25-26 stand rejected as obvious over Brock et al. in view of Hasegawa, Domsch et al., and Ansmann et al. The rejection is respectfully traversed. Claim 1 sets forth a microemulsion which includes a microemsulion comprised of components (A)-(B) and an additive selected from the group of one or more UV filters, and antidandruff substance and mixtures thereof. The Examiner in the Office Action recognizes that the primary reference to Brock fails to teach UV filters, antidandruff agents or mixtures thereof, but relies on the secondary references to Hasegawa, Domsch and Ansmann for their teachings of any dandruff agents and secondary light filters, i.e., UV filters to supply the deficiencies of Brock. The buttress of the rejection is that it would have been obvious to one of ordinary skill in the art to incorporate the UV filters and/or antidandruff substances of the secondary references into the composition of Brock. The Examiner goes on to state that the motivation to make such an incorporation is that a skilled artisan would have reasonable expectation of successfully producing a stable medicinal-dermalogical microemulsion by incorporating UV filters and/or any dandruff agents of the second references.

Attached to this Amendment is the Declaration (Brock Declaration) under 37 CFR §1.137 of Dr. Michael Brock, a named inventor on the application. Accompanying the Brock Declaration are a number of exhibits which reflect:

- An investigation of the Efficacy of Six Antidandruff Shampoos and specifically the use of Climbazole and Niacinamide as antidandruff agents described in Exhibits A and B.

- An investigation of the Efficacy of Three Antidandruff Shampoos and specifically Octopirox (the reaction product of 2-amino ethynol with 1-hydroxy-4-methyl-6-(2, 4, 4-trimethylpetyl) pyrodione as antidandruff agents. These test results are set forth in Exhibits C and D; and

- The testing of UV Filters specifically, Parsol MCX. These test results are set forth in the Exhibits E and F.

Also attached to the Brock Declaration is Exhibit G, a copy of an article entitled Sunscreen Formulation and Testing.

The Brock Declaration and the accompanying Exhibits A-F clearly establish that the microemulsion compositions set forth in (A-D) of Claim 1 (Claimed Microemulsion) produced unexpected results vis-à-vis the incorporation of antidandruff shampoo preparation (Exhibits A and B). Specifically, as explained in the Brock Declaration and set forth in Exhibit A attached

thereto, antidandruff shampoos produced using the Claimed Microemulsion (Products 3-6) show antidandruff efficacy the same as that achieved with conventional shampoo preparations (Products 1 and 2) even though the antidandruff agent in Products 3-6 is present in amounts of 2/3 and even as small as 1/3 of those used in a conventional shampoo preparation, Products 1 and 2.

The Examiner's attention is respectfully directed to a comparison of Product 1, a conventional shampoo preparation containing 0.75 wt.% Climbazole with Products 5 and 6 containing 0.25 wt.% and 0.5 wt.% Climbazole, respectively. Similar results are obtained when the antidandruff agent is Niacinamide wherein Product 2, the conventional shampoo preparation, contains 0.75 wt.% Niacinamide while Products 3 and 4 using the Claimed Microemulsion contain 0.25 wt.% and 0.5 wt.% Niacinamide, respectively. In effect, the data in Exhibits A-D clearly demonstrate that by incorporating common antidandruff agents, e.g., Climbazole and Niacinamide in the Claimed Microemulsions, unexpected results are achieved.

As pointed out in the Brock Declaration, the skilled artisan, of which Dr. Brock is clearly one, would not expect that by using the Claimed Microemulsion, one could achieve substantially the same antidandruff efficacy as conventional antidandruff shampoos when the amount of the antidandruff agent was reduced so dramatically. Exhibits C and D are similar to Exhibits A and B in that the efficacy of three antidandruff shampoo compositions was tested, the test procedures being set forth in Exhibit C, the composition of the three compositions being set forth in Exhibit D. Exhibit C clearly shows that one achieves essentially the same antidandruff efficacy in the products employing the Claimed Microemulsion, e.g., Products B and C, with markedly reduced

amounts of the active antidandruff agent Octopirox, as compared with a conventional antidandruff shampoo also containing Octopirox (Product A). Again as pointed out in the Brock Declaration, the results set forth in Exhibits C and D are unexpected and would not be anticipated by the skilled artisan.

As Dr. Brock has pointed out in the Brock Declaration, and with respect to Exhibits A-D, the expected result of the skilled artisan would have been that to achieve the same antidandruff efficacy as demonstrated by the conventional shampoo preparations, the same amount of active antidandruff agent would be necessary when used with the Claimed Microemulsion. As shown in Exhibits A-D and pointed out by Dr. Brock, that clearly is not true.

As to Exhibits E and F, and again as pointed out by Dr. Brock, Exhibit E sets out a comparative test between two shower gels identified as Duschgel 1 and Duschgel 2, both compositions being microemulsions according to the present invention, Duschgel 2 containing a commonly used sunscreen agent, Parsol MCX. Exhibit E of the Brock Declaration, gives the compositions of Duschgel 1 and Duschgel 2.

Again referring to the Brock Declaration and as stated by Dr. Brock, on page 3 of Exhibit F, Duschgel 2, using the Claimed Microemulsion and the sunscreen agent, Parsol MCX, exhibits UV filtering capacity twice as high as the straight microemulsion without any sunscreen additive. This is clearly surprising, as pointed out by Dr. Brock, since shower gels are intended to be rinsed off and accordingly the residence time on the skin is relatively short. However, as demonstrated by the results of Exhibits E and F, if one employs the Claimed Microemulsion as the carrier for the sunscreen agent, even after rinsing, significant, residual protection against UV

radiation remains on the skin. Again as stated by Dr. Brock, the skilled artisan would have no reason to believe that by incorporating a sunscreen agent into the Claimed Microemulsion of the present invention, such lasting UV protection would be obtained, i.e., one would expect that in the rinsing step the sunscreen agent would be removed leaving little to no residual protection against UV radiation.

With respect to Exhibit G, that article points out that a composition with an SPF of 2 absorbs 50% of UV radiation while the composition with an SPF of 3 to 4 absorbs 70% of the UV radiation. Thus, and again as set forth in the Brock Declaration, markedly increased protection against UV radiation is achieved when a UV filter is included in the Claimed Microemulsions of the present invention. Reiterating, this is unexpected since as Dr. Brock has pointed out, shower gels are always rinsed off after use and their application time to the body is relatively short, the expected result being that no residual protection against UV radiation would be obtained.

As the Federal Circuit said in *Singh v. Break*, 317 F.3d 1134, 1346; 65 USPQ 2d 1641 (Fed. Cir. 2003)

> "Whether or not a claimed invention provides 'unexpected results' (is) relevant in determining whether or not a claimed invention would have been obvious."

It is respectfully submitted that the Brock Declaration clearly and unequivocally establishes unexpected results and establishes that Claims 1-12, and 25-26 are patentable over Brock et al. in view of Hasegawa, Domsch et al. and Ansmann et al. It is further respectfully

submitted that obviousness over the references of record cannot be established by resorting to the seven rationales set forth in the examination guidelines for determining obviousness under 35 USC §103 in view of the Supreme Court decision in *KSR International Co. v. Teleflex, Inc.* as more fully set forth in the Federal Register/Volume 72, No. 195/Wednesday, October 10, 2007/Notices. To the extent any of those rationales would have any application to a determination of obviousness *vel non* of the claims of the present application, it is respectfully submitted that they have been completely rebutted by the Brock Declaration.

Applicant notes the double patenting rejection and respectfully requests that the filing of a terminal disclaimer to overcome that rejection be held in abeyance pending the indication of allowable subject matter.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims are in condition for allowance, which is hereby earnestly solicited and respectfully requested.

Respectfully submitted,

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